

## § 32.21

## 10 CFR Ch. I (1–1–16 Edition)

material identifying, by name and address, each person to whom byproduct material is transferred for use under § 30.18 of this chapter or the equivalent regulations of an Agreement State and stating the kinds, quantities, and physical form of byproduct material transferred.

(b) The licensee shall file a summary report with the Director of the Office of Nuclear Material Safety and Safeguards by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the materials are transferred for use under § 30.18 or equivalent regulations of an Agreement State.

(c) For each radionuclide in each physical form, the report shall indicate the total quantity of each radionuclide and the physical form, transferred under the specific license.

(d)(1) The licensee shall file the report, covering the preceding calendar year, on or before January 31 of each year. In its first report after December 17, 2007, the licensee shall separately include the total quantity of each radionuclide transferred for transfers in prior years not previously reported to the Commission.

(2) Licensees who permanently discontinue activities authorized by the license issued under § 32.18 shall file a report for the current calendar year within 30 days after ceasing distribution.

(e) If no transfers of byproduct material have been made under § 32.18 during the reporting period, the report must so indicate.

(f) The licensee shall maintain the record of a transfer for one year after the transfer is included in a summary report to the Commission.

[72 FR 58488, Oct. 16, 2007, as amended at 73 FR 5719, Jan. 31, 2008; 73 FR 42673, July 23, 2008]

### **§ 32.21 Radioactive drug: Manufacture, preparation, or transfer for commercial distribution of capsules containing carbon-14 urea each for “in vivo” diagnostic use for humans to persons exempt from licensing; Requirements for a license.**

(a) An application for a specific license to manufacture, prepare, process, produce, package, repack, or transfer for commercial distribution capsules containing 37 kBq (1 µCi) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process) each for “in vivo” diagnostic use, to persons exempt from licensing under § 30.21 of this chapter or the equivalent regulations of an Agreement State will be approved if:

(1) The applicant satisfies the general requirements specified in § 30.33 of this chapter, provided that the requirements of § 30.33(a) (2) and (3) of this chapter do not apply to an application for a license to transfer byproduct material manufactured, prepared, processed, produced, packaged, or repackaged pursuant to a license issued by an Agreement State;

(2) The applicant meets the requirements under § 32.72(a)(2) of this part;

(3) The applicant provides evidence that each capsule contains 37 kBq (1 µCi) carbon-14 urea (allowing for nominal variation that may occur during the manufacturing process);

(4) The carbon-14 urea is not contained in any food, beverage, cosmetic, drug (except as described in this section) or other commodity designed for ingestion or inhalation by, or topical application to, a human being;

(5) The carbon-14 urea is in the form of a capsule, identified as radioactive, and to be used for its radioactive properties, but is not incorporated into any manufactured or assembled commodity, product, or device intended for commercial distribution; and

(6) The applicant submits copies of prototype labels and brochures and the NRC approves these labels and brochures.

(b) Nothing in this section relieves the licensee from complying with applicable FDA, other Federal, and State requirements governing drugs.

[62 FR 63640, Dec. 2, 1997, as amended at 66 FR 64738, Dec. 14, 2001]